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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/616,784

07/10/2003

William P. Van Antwerp

G&C 130.62-US-01

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09/17/2009

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EXAMINER

OSINSKI, BRADLEY JAMES

ART UNIT

PAPER NUMBER

3767

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/616,784	<b>Applicant(s)</b> VAN ANTWERP, WILLIAM P.	
	<b>Examiner</b> BRADLEY J. OSINSKI	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-9 and 36-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-9 and 36-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. Claims 1, 3-6, 8, 9 and 37-41 rejected under 35 U.S.C. 103(a) as being unpatentable over Gu et al (World Journal of Microbiology and Biotechnology) in view of Steinberg et al (Biodegradation).

a. Regarding claim 1, Gu discloses a catheter coated with a heavy metal (page 177) that is coated with lectins capable of binding microorganisms that form a biofilm on the surface of a medical device. The lectins are disposed in a biodegradable polymer of cellulose acetate in acetone (see Andrady and Applicant's specification) that is capable of sloughing away from the medical device when the lectin is bound to a compound produced by a microorganism. Gu also discloses lectins may be used to enhance adhesion of bacteria that from biofilms (Page 177). While Gu substantially discloses the apparatus as claimed, it does not disclose an expectation of success if the lectins had enhanced absorption of microorganisms. However, a scientific paper by Steinberg et al discloses a brief overview of biofilm inhibition methods. One is the continuous shedding of outer layers, removing any attached epibiota (Page 213). Thus Steinberg presents evidence that increasing the absorption of bacteria on a surface that is degradable/sloughing away (as Gu gives examples of) is a way of inhibiting biofilm growth on the surface of a device/organism. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Gu to give the lectins improved adhesive properties

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as taught in Gu itself so as to improve biofilm inhibition of the device as known in the art via Steinberg.

- b. Regarding claim 3, Cellulose acetate in acetone is a biocompatible polymer that has a controllable rate of degradation based upon the various controllable factors of the polymer (degree of substitution, amount of solvent, etc...).
- c. Regarding claims 4 and 5, Gu also discloses silver ions as an antibiotic agent.
- d. Regarding claim 6, Gu discloses the microorganism *Pseudomonas aeruginosa*.
- e. Regarding claim 8, The device of Gu is capable of being implanted.
- f. Regarding claim 9, Gu discloses a catheter.
- g. Regarding claim 37, Gu discloses the catheter being made of various substances, including the biostable polymeric material polytetrafluoroethylene (page 174)
- h. Regarding claim 38, see claims 1 and 37 above.
- i. Regarding claim 29, see claim 27 above.
- j. Regarding claim 40, see claim 1 above.
- k. Regarding claim 41, as the composition of Gu inhibits the attachment of *P. aeruginosa* to the mechanical structure relative to the mechanical structure not coated with the composition, it is apparent that the lectin is disposed on a region

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of the device having a mechanical structure that is compatible with the adherence of microorganisms.

2. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gu et al (World Journal of Microbiology and Biotechnology) and Steinberg et al (Biodegradation) as applied to claim 1 above, and further in view of Schrier et al (6,197,598).

l. Regarding claim 7, While Gu substantially discloses the apparatus as claimed, it does not disclose the specific lectins concanavalin A or wheat germ agglutinin. However, Schrier et al discloses concanavalin A as being a binder lectin for *Pseudomonas aeruginosa* (Col. 10 line 67 and Col.11 line 13).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use concanavalin A as the lectin of Gu as taught by Schrier et al as concanavalin A is a known lectin that binds *Pseudomonas aeruginosa*.

3. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gu et al (World Journal of Microbiology and Biotechnology) and Steinberg et al (Biodegradation) as applied to claim 1 above, and further in view of Cioanta et al (2002/0082556).

m. Regarding claim 36, While Gu substantially discloses the apparatus as claimed such as inhibition of bacterial attachment to steel (page 174), it does not disclose the catheter being composed partially of titanium or stainless steel.

However, Cioanta discloses stainless steel as a catheter material that can utilize a material to inhibit formation of biofilms (paragraphs 102 and 121). Therefore, it would have been obvious to one of ordinary skill in the art at the time the

invention was made to use the biofilm of Gu with a stainless steel catheter such as that of Cionata as there is only the expectation of reducing biofilm formation upon the stainless steel catheter.

***Response to Arguments***

4. Applicant's arguments filed 5-26-2009 have been fully considered but they are not persuasive.

n. Applicant argues Gu is not applicable to the rejection because the Examiner has not considered the reference as a whole such that Gu actually teaches away from the combination. The Examiner does not find this persuasive. One having read only parts of Gu would indeed see that the use of lectins to block bacterial adhesion is a method of protecting catheters. However, one carefully reading the entire article would recognize that lectins also contribute to enhancing adhesion. This is the very substance of routine scientific experimentation, in both academic and professional circles, and falls within the skill of one of ordinary skill in the art since this suggests a different route by which lectins may be used to protect catheters.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRADLEY J. OSINSKI whose telephone number is (571)270-3640. The examiner can normally be reached on M-Th 8AM-5PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley J Osinski/

Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767